REMARKS

Claims 1-32 are pending in this application. Claims 1-32 have been rejected under 35 U.S.C. § 103. Claims 1, 12 and 15 have been amended. Claim 33 has been added. The specification has been amended. No new matter has been added. Reexamination and reconsideration are respectfully requested.

Specification

Applicant has amended the specification to correct a typographical error as shown above. No new matter has been added.

Rejection under 35 U.S.C. § 103.

The Examiner has rejected Claims 1-32 under 35 U.S.C. § 103(a) as being unpatentable over Gambale et al., U.S. Patent No. 6,692,520, in view of Ellinwood, Jr., U.S. Patent No. 4,003,379, and Penner et al., U.S. Patent No. 6, 431,175. Applicant has amended Claims 1, 12 and 15. No new matter has been added. The rejection is respectfully traversed with respect to Claim 29.

As amended, Claim 1 recites a method for non-vascular implant of a sensor comprising, *inter alia*, implanting an implant unit in an area of a body without passing the implant unit through a vascular system, directing a sensor into a foreign body capsule, and connecting the sensor to the implant unit subsequent to formation of the foreign body capsule. Similarly, Claim 12 recites a method for non-vascular implant of a sensor comprising, *inter alia*, incising an area of a body large enough for inserting an implant unit; incising an area remote from a sensor location for inserting a sensor; directing the sensor into a body cavity, disposing the sensor in a location remote from an incision through which the sensor is directed without passing the sensor through a vascular system; connecting the sensor to the implant unit; and inserting the implant unit into the body. Claim 15 recites a non-vascular implant system comprising, *inter alia*, an implant unit and a sensor, the sensor being separate from and connectible to the implant unit, and wherein the sensor is configured to be placed in an area of the human body without passing the

sensor through a vascular system. These features are not disclosed or suggested, individually or in combination, in Gambale et al., Ellinwood, Jr., and Penner et al.

Gambale et al. is directed toward systems and methods for stimulating intramuscular angiogenesis by placing a biocompatible device within the tissue of a muscle. In Gambale et al., an implantable body 14 is passed via a delivery system 18 through the aorta 12 and placed within the myocardium 10. (Gambale et al., Figure 1A; column 10, lines 12-22.)

The implantable body 14 in Gambale et al. is simply a composition of biocompatible material. (Gambale et al., column 11, lines 5-28.) There is no sensor disclosed or suggested in Gambale et al., nor does the implantable body 14 connect to anything. Moreover, the path taken to reach the aorta 12 and implant the implantable body 14 into the myocardium 10 is the arterial system. (Gambale et al., column 10, lines 24-30.) Use of the arterial system, or any other part of the vascular system, as a pathway for an implantable unit can be painful and traumatic (see Applicant's specification, BACKGROUND section). Indeed, amended Claims 1, 12 and 15 recite, *inter alia*, that implantation is achieved *without* passing through the vascular system and, thus, avoid vascular placement, i.e., the type of placement for implantable units specifically disclosed by Gambale et al. There is no connecting of a sensor to an implantable device after the implantable unit has been implanted, as recited in amended Claims 1 and 15, or disposing of a sensor or implant unit without passing the sensor or implant unit through a vascular system, as recited in amended Claims 1, 12 and 15, in Gambale et al.

Ellinwood, Jr. is directed toward an apparatus for dispensing drugs and other medications within a patient. While Figures 12 and 13 of Ellinwood, Jr. show an infusion pump that includes sensors 250, the sensors 250 are an integral part of the pump. Thus, the pump and sensors 250 form one unit and cannot be separated from one another. Moreover, although Ellinwood, Jr. is, for the most part, silent with respect to sensor placement, he does suggest vascular placement by referring to vascular surgery. (Ellinwood, Jr., column 7, lines 44-51.) Thus, as was the case with Gambale et al., Ellinwood, Jr. suggests vascular implant, something embodiments of the present invention as recited in amended Claims 1, 12 and 15 seek to avoid.

Penner et al. is directed toward a system for monitoring, directing and controlling a dose of radiation in a medical procedure. While Penner et al. discloses sensors 102 implanted within a body (see Penner et al. Figures 1A-1C), Penner et al. is completely silent on the placement of the sensors and has does not disclose or suggest that the sensors may be connected to an implantable device within the patient's body.

In contrast, amended Claim 1 recites implanting an implant unit into an area of the body without passing the implant unit through a vascular system, allowing a foreign body capsule to form around the area of the implant unit directing the sensor into the foreign body capsule and connecting the sensor to the implant unit subsequent to formation of the foreign body capsule. All of the references cited by the Examiner are silent on, at least, connecting a sensor to an implanted unit subsequent to formation of a foreign body capsule around the implant unit. Similarly, Claim 12 recites disposing the sensor in a location remote from an incision through which the sensor is directed without passing the sensor through a vascular system, connecting the sensor to an implant unit and inserting the implant unit into a body. All of the references cited by the Examiner are silent on, at least, disposing the sensor in a location remote from an incision through which the sensor is directed without passing the sensor through a vascular system, connecting the sensor to an implant unit and inserting the implant unit into a body. Claim 15 is a system claim that relates to method Claim 1. All of the references cited by the Examiner are also silent with respect to the features of Claim 15.

Moreover, even assuming, *arguendo*, that the combination of the cited references disclose all of the features of amended Claims 1, 12 and 15, there is no motivation to combine the references. The Gambale et al. device is a single, solitary composition of biocompatible material. The biocompatible material does not sense anything, nor does it connect to another device as do the sensors in Ellinwood, Jr. and Penner et al. Accordingly, one of ordinary skill in the art would have no motivation to combine the sensing devices of Ellinwood, Jr. and Penner et al. with the non-sensing, solitary device of Gambale et al.

Thus, there are features recited in amended Claims 1, 12 and 15 that are not disclosed or suggested in either Gambale et al., Ellinwood, Jr., or Penner et al., individually or in

combination. Because the references cited by the Examiner do not disclose features recited in amended Claims 1, 12 and 15, the combination of these references cannot disclose all of the features recited in amended Claims 1, 12 and 15. Moreover, there is no motivation to combine the references cited by the Examiner. Accordingly, a *prima facie* case of obviousness has not been made using these references with respect to Claims 1, 12 and 15. Claims 1, 12 and 15, and the claims depending directly or indirectly therefrom, cannot, therefore, be obvious in light of these references.

Claim 29 recites a method for non-vascular implant of a sensor comprising, *inter alia*, incising an area of a body large enough for inserting an implant unit; creating a tunnel in subcutaneous tissue; directing the sensor through the tunnel; connecting the sensor to the implant unit; and inserting the implant unit into the body. None of the references cited by the Examiner disclose or suggest creating a "tunnel" in subcutaneous tissue or directing a sensor through the tunnel. Thus, Claim 29 recites features not disclosed or suggested in any of the references cited by the Examiner. Thus, the combination of these references cannot disclose or suggest all of the features of Claim 29. Claim 29 and claims depending directly or indirectly therefrom are, therefore, not obvious in light of the references cited by the Examiner.

Applicant has added Claim 33. No new matter has been added. Applicant believes Claim 33 to be allowable over the art cited by the Examiner.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 06-1447. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 06-1447. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 06-1447.

Respectfully submitted,

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